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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/728,179

12/03/2003

Herbert W. Harris

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06/27/2008

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EXAMINER

SOROUGH, LAYLA

ART UNIT

PAPER NUMBER

1617

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/728,179	<b>Applicant(s)</b> HARRIS ET AL.	
	<b>Examiner</b> LAYLA SOROUGH	<b>Art Unit</b> 1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 March 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 13-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/18/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The response filed March 28, 2008 presents remarks and arguments submitted to the office action mailed December 31, 2007 is acknowledged.

Claims 1-40 are pending.

Applicant's arguments over the 35 U.S.C. 112 second paragraph rejection of Claims 2 and 7 is not persuasive. Therefore, the rejection is maintained for the reasons of record.

Applicant's arguments over the 35 U.S.C. 102 (b) rejection of Claims 1 and 12 over Korosi et al. (US Pat No. 4,423,044) is not persuasive. Therefore, the rejection is herewith maintained for the reasons of record.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of 2-11 over Korosi et al. (US Pat No. 4,423,044) is not persuasive. Therefore, the rejection is herewith maintained for the reasons of record.

Applicant's presented no arguments over the Obvious Double Patenting rejection of US Pat. No. 6864251. Therefore, the rejection is herewith maintained for the reasons of record.

Applicant's argues US Applic. No. 10/309573 is a duplicate of US Pat. No. 6864251. Therefore, the rejection is herewith withdrawn.

Applicant's argues US Applic. No. 10/728286 has gone abandoned. Therefore, the rejection is herewith withdrawn.

Applicant's arguments over the Obvious Double Patenting rejection of US Applic. No. 10/727940 is not persuasive. Therefore, the rejection is herewith maintained for the reasons of record.

The rejections of record are restated below for Applicants convenience:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation "substantially free" renders the claim vague and indefinite.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Korosi et al. (US Pat No. 4,423,044).

Korosi et al. discloses a pharmaceutical composition containing an active ingredient a 3,4-Dihydro-5H-2,3-benzodiazepine derivatives of the formula (I) and pharmaceutically acceptable acid addition salts thereof, wherein R represents a phenyl

group optionally carrying one or two substituents selected from the group consisting of halogen, hydroxy, C1-4 alkoxy and benzyloxy; a furyl or a thienyl group. R1 stands for a hydrogen atom or a C1-4 alkyl group, R2 and R3 each represent hydrogen atom, C1-4 alkoxy, C4-7 cycloalkoxy or benzyloxy group together with a conventional inert, non-toxic, solid or liquid carrier and/or additive. Hence, the compound of formula I wherein the R represents a phenyl group carrying two substituents selected from a hydroxyl, a C1 alkoxy, R1 stands for a C2 alkyl group, R2 and R3 represents two C1 alkoxy groups (col 9 claim 1 and col 10 claim 9).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korosi et al. (US Pat No. 4,423,044) as applied to claims 1 and 12 above.

Korosi et al. fails to teach (R) or (S)- 1-(3-hydroxy-4-methoxyphenyl)-4-methyl-5-ethyl-7,8- dimethoxy-5H-2,3-benzodiazepine.

The difference between the present claims and prior art is that applicants claim the R and S isomer whereas the prior art discloses the racemate. However, it is generally known in the art that normally, one of the enantiomers of a racemate would possess a disproportionate amount of the desired biological activity. This would

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motivate one of ordinary skill to isolate the separate enantiomers in order to determine which of the two is most effective for the desired purpose. In addition, the isomer/enantiomer of a racemate is prima facie obvious. In re Adamson, 125 USPQ 233 (1960).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6864251 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the invention herein is drawn to a pharmaceutical composition comprising a pharmaceutically acceptable carrier and 1-(3-hydroxy-4-methoxyphenyl)-4-methyl-5-ethyl-7,8- dimethoxy-5H-2,3-benzodiazepine, or a pharmaceutically acceptable salt

thereof whereas the prior art teaches a method of treating a individual afflicted with an inflammatory disorder mediated by LTB.sub.4 comprising administering to said individual an effective amount of at least one compound inclusive of 1-(3-hydroxy-4-methoxyphenyl)-4-methyl-5-ethyl-7,8- dimethoxy-5H-2,3-benzodiazepine, or a pharmaceutically acceptable salt thereof.

It would have been obvious to a skilled artisan that the identical compound would be useful as a pharmaceutically acceptable compound as claimed.

Claims 1-6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 13 of U.S. Patent Application No. 10/727940. Although the conflicting claims are not identical, they are not patentably distinct from each other because the invention herein is drawn to a pharmaceutical composition comprising a pharmaceutically acceptable carrier and 1-(3-hydroxy-4-methoxyphenyl)-4-methyl-5-ethyl-7,8- dimethoxy-5H-2,3-benzodiazepine, or a pharmaceutically acceptable salt thereof whereas the prior art teaches a method of treating an individual afflicted with an inflammatory disorder comprising administering to said individual an effective amount of at least one compound inclusive of 1-(3-hydroxy-4-methoxyphenyl)-4-methyl-5-ethyl-7,8- dimethoxy-5H-2,3-benzodiazepine, or a pharmaceutically acceptable salt thereof.

It would have been obvious to a skilled artisan that the identical compound would be useful as a pharmaceutically acceptable compound as claimed.

### ***Response to Arguments***

Applicant's arguments filed March 28, 2008 have been fully considered. The response to the arguments is as discussed below:

Applicant argues that Korosi et al. does not disclose the compound 1-(3-hydroxy-4-methoxyphenyl)-4-methyl-5-ethyl-7,8-dimethoxy-5H-2,3-benzodiazepine by name or structure. It is Examiners contention that the genus taught by claim 1 and 9 of Korosi et al. has an identical core structure and substituents that are so small in number that one could readily envisage the claimed species.

Applicant's argument over claims 2-11 rejections depends on the validity of the previous arguments which were not found persuasive.

Applicant argues the Obvious Double Patenting rejection of US Applic. No. 10/727940 is premature since the conflicting claims have not yet been patented. Examiner states that this is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome a provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. (See 37 CFR 1.130(b)).

The arguments are not persuasive and the rejection is made **FINAL**.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Conclusion***

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617